REMARKS

This responds to the Final Office Action dated February 16, 2011.

Claims 1, 13, 14 and 21 are amended. No claims are canceled or added. As a result, claims 1, 3-18 and 20-26 are now pending in this application.

The Rejection of Claims Under § 102

Claims 1, 3, 5-8, 10-11, 13, 17 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischer et al. (5,697,918). Applicants respectfully traverse this rejection.

Claim 1 presently recites a coupling syringe system comprising, among other things, a first and second syringe, "…wherein the first syringe and the second syringe are each sized to contain a single dose…configured for back and forth transfer of a first and a second composition between the first syringe and second syringes, wherein a mixing volume of the first and second compositions is substantially fully transitioned between the first and second syringes in corresponding first and second mixing configurations: in the first mixing configuration, the mixing volume is substantially fully retained within the first syringe, and in the second mixing configuration, the mixing volume is substantially fully retained within the second syringe."

Applicants respectfully assert that Fischer neither structurally nor functionally discloses the claimed syringe system, where two compositions are transferred back and forth between two single dose syringes, and where each syringe is configured to substantially fully retain the entire mixing volume. Instead, Fischer only discloses the unidirectional transfer of a specific amount of a single composition from a bulk storage vessel into an empty dose administration syringe (see column 4, line 19 to column 5, line 8). The dose syringe 52 of Fischer does not include any composition therein until the composition from the storage syringe is unidirectionally transferred into it (see FIGS. 5, 6, 8, 9, 11 and 12).

Additionally, Applicants respectfully assert that Fischer fails to disclose the mixing configurations recited in the instant claims. Specifically, Fischer does not disclose "in the first mixing configuration, the mixing volume is substantially fully retained within the first syringe, and in the second mixing configuration, the mixing volume is substantially fully retained within the second syringe." Indeed, these two mixing configurations are not possible in the Fischer

system, because Fischer only discloses a single composition, and because the dose syringe would be unable to substantially fully retain the transitioned volume of the bulk composition from the bulk storage syringe (see FIGS. 5 and 9). The bulk amount of material stored within the storage syringe would push the plunger out of engagement with the dose syringe and thereby allow the composition to escape the dose syringe.

Thus, because Fischer fails to disclose every element of Applicants' claim 1, the reference cannot anticipate such claim. Claims 3, 5-8, 10-11, 13, 17 and 20 are dependent on claim 1 and are believed to be patentable over Fischer for at least the reasons stated above. Applicants respectfully request the reconsideration and withdrawal of this rejection, and the allowance of claims 1, 3, 5-8, 10-11, 13, 17 and 20.

The Rejection of Claims Under § 103

Claims 1, 3-14, 17-18, 20-22, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beller (5,425,580) in view of Fitoussi et al (5,984,373). Applicants respectfully traverse this rejection.

The cited Beller and Fitoussi documents, alone or in combination, fail to teach or suggest all of Applicants' claimed elements. To this end, Applicants submit that in contrast to the Office Action's assertion, Beller fails to disclose certain aspects of the claimed invention beyond a first syringe having a locking ring. Claims 1 and 21, for example, presently recite a syringe system comprising, among other things, both first and second syringe plungers being configured to move to a position at the distal end of the respective syringe…wherein a mixing volume of the first and second compositions is substantially fully transitioned between the first and second syringes in corresponding first and second mixing configurations: in the first mixing configuration, the mixing volume is substantially fully retained within the first syringe, and in the second mixing configuration, the mixing volume is substantially fully retained within the second syringe. Stated differently, the plungers are configured to move all the way to the distal ends of Applicants' syringes to effectuate complete back and forth transfer of the compositions thereby providing a mixed composition. In contrast, Beller recites a mixing chamber non-detachable from a first syringe that does not allow a plunger to move to the distal end of the syringe. For instance, Beller clearly recites:

> The invention therefore relates to apparatus for preparing a dosage form from micro bubble echo contrast media comprising a first syringe and a mixing chamber which is unreleasably connected thereto.

(Beller at column 2, lines 13-16; emphasis added.) Beller expressly requires the use of a mixing chamber including transversely-oriented mixing elements between a first syringe and a second syringe, as is clearly indicated in the statement:

> [The stated] objects [of Beller] are achieved according to the invention by the apparatus for preparing a dosage form for echo contrast media comprising a syringe and a mixing chamber which is unreleasably connected thereto and contains a predetermined amount of gas, plus a second syringe . . . The mixing chamber is preferably tubular and has mixing elements in its inner lumen.
>
> In a preferred embodiment, the mixing elements are designed in the form of spikes, that is to say the mixing elements preferably stand at right angles to the inner wall of the mixing chamber and thus point in the direction of the long axis of the mixing chamber tube.

(Beller at column 2, lines 7-29; emphasis added). Due to the perpendicularly-oriented mixing elements, a first syringe plunger of Beller is precluded from fully advancing to a distal end position of such syringe near a male end portion, thereby leaving waste in the mixing chamber and failing to substantially fully transition the mixing volume between the two syringes. Thus, there is no disclosure or suggestion of a configuration in Beller whereby a mixing volume is substantially fully retained in the second syringe of Beller, as required by Applicants' claims. Fitoussi does not remedy these deficiencies of Beller. Applicants thus respectfully request withdrawal of this rejection under 35 U.S.C. § 103(a) and the allowance of claims 1, 3-14, 17-18, 20-22, 25 and 26.

Claims 15-16 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beller in view of Fitoussi and in further view of Cha et al (5,702,717). Applicants respectfully traverse this rejection.

As discussed above, the Beller and Fitoussi documents fail to disclose or suggest all the elements of Applicants' claims. Cha fails to remedy these deficiencies. In addition, Applicants further submit that there is insufficient legal motivation to combine Cha with the references, in particular with Beller. Beller expressly requires the use of a mixing chamber including transversely-oriented mixing elements between a first syringe and a second syringe, as discussed

above. Due to the perpendicularly-oriented mixing elements, a first syringe plunger of Beller is precluded from fully advancing to a distal end position of such syringe, thereby failing to substantially fully transition the mixing volume between the two syringes and leaving waste in the mixing chamber.

Applicants submit that even very small amounts of waste would be troubling for at least two reasons. First, drugs like leuprolide acetate are very powerful and thus are administered at very small doses that must be measured very precisely and administered accurately. A small variation in the amount of leuprolide administered, such as that which could be caused by using the mixing chamber of Beller, could cause significant negative effects to the patient. Second, any waste would result in misuse of an expensive medicament. Thus, to be used with leuprolide acetate, the coupled syringe system must not result in a significant loss, which teaches against using the syringe system of at least Beller.

Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 103(a) and the allowance of claims 15-16 and 23-24.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's representative at (612) 371-2106 to facilitate prosecution of this application.

If necessary, please charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

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